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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			KIM, JOHN	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/788,866

Applicant(s)

MOLZ ET AL.

Examiner

John Kim

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 38-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/27/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/10/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 38-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 19, 2005.

Applicant's election with traverse of claims 38-58 in the reply filed on December 19, 2005 is acknowledged. The traversal is on the ground(s) that "there will be no significant extra burden in searching and examining both sets of claims." This is not found persuasive because "a serious burden on the examiner may be shown by prima facie if the examiner shows separate classification." (See MPEP section 808.02). In the instant case, the inventions have separate classifications, as noted in the previous office action.

The requirement is still deemed proper and is therefore made FINAL.

After further review, examiner removes the election of species. However it is noted that election of species is proper since applicant had two types of cords, a single fiber and multiple fiber, as seen in the figures.

Claim Objections

In claims 21 and 22 there exist an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble of claim 1, line 1, applicant recites "a tether" with the two adjacent bone

Art Unit: 3733

portions being only functionally recited, i.e. "for orthopedic treatment to secure to two adjacent bone portions....", thus indicating that the claim is directed to the subcombination, "a tether ". However, in claim 21 and 22, applicant positively recites the two bone portions as part of the invention, i.e. "the tether... wherein the two bone portions include ...", thus indicating that the combination, tether and two bone portions, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Since claiming the combination of the tether and the two bone portions makes such claim(s) directed to non-statutory subject matter, applicant should amend the claims so as to remove all positive recitations of the two bone portions. As such, the claim(s) would be directed to the subcombination, the tether, and will be considered as such for examination purposes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 20, 23-28, and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avellanet (US Pat 6137060, in IDS) in view of Butters (US Pat 5296292).

In regards to claim 1, Avellanet teaches of a tether with a cord (110) and a first sheath (102, 104, 106, 108) that encases the cord, and a radiopaque element (NiTi,

Art Unit: 3733

see abstract). However, Avellanet fails to teach about the first sheath providing an abrasion resistant coating. Butters teaches of having a tether where the "layer may be rendered abrasion resistant by sizing the article through a die to smooth and toughen its surface or by coating with an abrasion resistant material." (col 2:6-9) Thus, it would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Avellanet in view of Butters, in order to make a tether last longer and maintain its tensile strength. Optionally, a second sheath can be applied. Though Avellanet may have not directly taught to apply a second sheath, one can merely repeat the process to apply a second sheath. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a second sheath, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

In regards to claim 2, with the second outer sheath having a larger diameter than the cord, it would be expected that the cord is slidably received within the second outer sheath. In regards to claim 3, with the first sheath having an abrasion resistant coating, it would be expected that the cord, which is elongate and defines a longitudinal axis, is free to move longitudinally with respect to the first sheath. In regards to claim 4, though Avellanet does not teach of having two sheaths frictionally engaged, Butters teaches of "coating with an adhesive layer." (col 3:55). Thus, it would have been obvious to one skilled in the art at the time the invention was made to construct the sheath of Avellanet

in view of Butters' addition of an adhesive layer in order to frictionally engage the two sheaths.

In regards to claim 5, Avellanet teaches of having a cord with a single fiber (wire). In regards to claim 6 and 7, Butters teaches the cord may "consist essentially of one or more strands of monofilament." (col 3:2-3) He further teaches "multiple strands may be braided" to provide the cord. (col 3:4-5) In regards to claim 8, 9, and 11-14, Avellanet teaches of having a tether made from strands of nickel-titanium alloy wire and from a strand of high density wire such as "gold, silver..." (col 3:58-61). Thus the high density (radiopaque element) wire is the cord and the plurality of alloy wire is the first sheath. Avellanet discloses the claimed invention except for the first sheath can comprise a radiopaque element. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a radiopaque element into the sheath, since it has been held that rearranging parts of an invention involves only routine skill in the art. In *re Japikse*, 86 USPQ 70. Avellanet teaches of using a single radiopaque element. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the tether of Avellanet having a plurality of radiopaque filaments to make a radiopaque element, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

In regards to claim 10, Avellanet and Butters both teach of having a tether with a cord, one or two sheaths, and a radiopaque element. However, they both do not teach the use of barium sulfate as the radiopaque element. It would have been obvious to

Art Unit: 3733

one having ordinary skill in the art at the time the invention was made to use barium sulfate as the radiopaque element, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In *re Leshin*, 125 USPQ 416.

In regards to claim 20, though Avellanet and Butters teach of having a tether with a cord, one or two sheaths, and a radiopaque element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sheath, cord, or both out of elastomeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In *re Leshin*, 125 USPQ 416.

In regards to claim 24-28 and 33-34, Butters teaches of using PFTE in the sheath, however, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make a cord with polymeric material, biodegradable material or non-biodegradable material and radiopaque element composed of biocompatible metallic fiber, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In *re Leshin*, 125 USPQ 416. In regards to claim 23, Avellanet teaches of make a tether that is flexible, thus the cord and the sheath are flexible. In regards to claim 25, Avellanet teaches of making a tether with the cord and sheath made of two different materials (silver/gold and NiTi).

In regards to claim 35, Avellanet teaches of using a radioactive element for the radiopaque element. However, he fails to teach the duration of the radioactivity. It

Art Unit: 3733

would have been obvious to one having ordinary skill in the art at the time the invention was made to make a radiopaque element with a duration of one month to five years, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In *re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In regards to claim 36 and 37, and as discussed above, Avellanet teaches of having a tether with a cord, a sheath with a plurality of fibers. Avellanet teaches of using a radiopaque filament or means for imparting radiolucency by using a higher density core wire preferably made of silver or gold. Avellanet fails to teach about having an abrasion resistant coating or a means for attaching the first sheath to the cord to provide an abrasion resistant coating to the cord. Butters teaches of using PTFE to add the smoothness to the cord and increase abrasion resistance. It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Avellanet in view of Butters, in order to make a tether last longer and maintain its tensile strength. It is noted that in both claims, applicant may be invoking 35 USC 112 6th with "means for" language. However, it is clear from this office action that radiolucency and abrasion resistant coating is taught by prior art, as established above and below.

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avellanet (US Pat 6137060) in view of Butters (US Pat 5296292) as applied to claim 1 above, and further in view of Holzhauser (US Pat 3968725).

In regards to claims 15 and 16, Avellanet does not teach that the sheath is fixedly secured to the cord. Furthermore, Holzhauer teaches that a sheath that is not fixedly secured to the cord, as seen in figure 2. The sheath (12) is braided over the inner braid (11), thus not fixedly secured. (col 3: 5-25) In regards to claim 17, Avellanet teaches that NiTi, as a fiber, is embedded into the outer sheath. In regards to claim 18, with the lack of being fixedly secured, the second sheath is free to move longitudinally with respect to the first sheath or cord.

Claims 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avellanet (US Pat 6137060) in view of Butters (US Pat 5296292) as applied to claim 1 above, and further in view of Burke et al (US Pat 6338734).

In regards to claim 19 and 22, Avellanet and Butters fail to teach to use their tethers to attach bone portions. Burke teaches of using tethers to attach bone fragments from surgery (see fig 1). It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Avellanet and Butters in view of Burke, in order to use a better tether to attach bone portions, which are too small for plate and anchors, together. As seen in figure 1, Burke teaches of reattaching the severed greater trochanter to the femur, part of an articulating joint.

Claims 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Avellanet (US Pat 6137060) in view of Butters (US Pat 5296292) as applied to claim 1 above, and further in view of Nastari et al (US Pat 4643178).

Art Unit: 3733

In regards to claim 21, Avellanet and Butters fail to teach to use their tethers to attach bone portions. Nastari teaches of using a tether to attach two vertebrae together (see fig 2 or 6). It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Avellanet and Butters in view of Burke, in order to use a better tether to attach bone portions, which are too small for plate and anchors, together.

Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avellanet (US Pat 6137060) in view of Butters (US Pat 5296292) as applied to claim 1 above, and further in view of Johnson et al (US Pat 4146022).

In regards to claim 29 and 30, Avellanet and Butters does not teach of using a bone fastener. Johnson teaches of using a bone fastener (30, see fig 3 or 4). It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Avellanet and Butters in view of Johnson, to provide a better means to secure the tether to the bone portions together. As seen in figure 1, Johnson teaches of using more than one bone fasteners. In regards to claim 31 and 32, though Avellanet never teaches of removing the first or second sheath, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the first sheath not secured to the bone portions or the second sheath not secured to two or more bone portions, since it has been held that rearranging parts of an invention involves only routine skill in the art. In *re Japikse*, 86 USPQ 70.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER